Louisiana Medicaid
Stimulants and Related Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Clinical authorization for **all** preferred and non-preferred agents for recipients younger than 7 years of age; **OR**
- Prior authorization for non-preferred agents for recipients 7 years of age and older.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Initial and Reauthorization Approval Criteria for ALL Stimulants and Related Agents (both preferred and non-preferred) for Children under 7 years of Age [except armodafinil (Nuvigil®), modafinil (Provigil®), pitolisant (Wakix®) or solriamfetol (Sunosi®)]:

- For amphetamine salt combo ER (generic and authorized generic for Adderall XR®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Adderall XR®; **OR**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The child has had *treatment failure* with at least one preferred product; **OR**
    - The child has had an *intolerable side effect* to at least one preferred product; **OR**
    - The child has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- The child has a diagnosis approved for the medication requested (see POS Edits); **AND**
- **ONE** of the following (due to this diagnosis) is true and is **stated on the request**:
    - Child has had a trial of behavioral therapy and has ongoing impairing and/or dangerous symptoms; **OR**
    - Child has started behavioral therapy but has extremely impairing and/or potentially dangerous symptoms; **OR**
    - Child has been referred to behavioral treatment but has extremely impairing and/or potentially dangerous symptoms that warrant treatment before therapy has had a chance to have an effect (with plan to follow up); **OR**
    - There are no known behavioral therapy resources available to this child, who has extremely impairing and/or potentially dangerous symptoms; **OR**
    - **ALL** of the following:
        - The child is 6 years of age; **AND**
        - The diagnosis for the requested medication is attention deficit hyperactivity disorder (ADHD); **AND**
        - By submitting this request, the provider attests that behavioral treatment has been prescribed in addition to the requested medication; **AND**
- By submitting the authorization request, the prescriber attests to the following:

- Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **AND**
- The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling;

OR

- For amphetamine salt combo ER (generic and authorized generic for Adderall XR®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Adderall XR®; **OR**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- The child has a diagnosis approved for the medication requested (see POS Edits); **AND**
- The prescriber **states on the request** that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of Initial and Reauthorization Approval for ALL Stimulants and Related Agents (both preferred and non-preferred) for Children under 7 years of Age [except armodafinil (Nuvigil®), modafinil (Provigil®), pitolisant (Wakix®) or solriamfetol (Sunosi®)]: 12 months or up to the recipient's 7th birthday, whichever is less

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Approval Criteria for Non-Preferred Stimulants and Related Agents [except armodafinil (Nuvigil®), modafinil (Provigil®), pitolisant (Wakix®) or solriamfetol (Sunosi®)] for Recipients 7 years of Age and Older:

- For amphetamine salt combo ER (generic and authorized generic for Adderall XR®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Adderall XR®; **OR**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**

- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber **states on the request** that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- The recipient has a diagnosis approved for the medication requested (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Non-Preferred Stimulants and Related Agents [except armodafinil (Nuvigil®), modafinil (Provigil®), pitolisant (Wakix®) or solriamfetol (Sunosi®)] for Recipients 7 Years of Age and Older

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of Initial and Reauthorization Approval for Non-Preferred Stimulants and Related Agents [except armodafinil (Nuvigil®), modafinil (Provigil®), pitolisant (Wakix®) or solriamfetol (Sunosi®)] for Recipients 7 Years of Age and Older: 12 months

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Approval Criteria for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®), Pitolisant (Wakix®) and Solriamfetol (Sunosi®)

- On the date of the request, the recipient age is:
    - 17 years of age or older for armodafinil or modafinil; **OR**
    - 18 years of age or older for pitolisant or solriamfetol; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**

    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber **states on the request** that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- The recipient has a diagnosis approved for the medication requested (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®), Pitolisant (Wakix®) and Solriamfetol (Sunosi®)

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of Initial and Reauthorization Approval for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®), Pitolisant (Wakix®) and Solriamfetol (Sunosi®): 3 months

References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from https://www.clinicalkey.com/pharmacology/

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; Retrieved from https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

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Revision / Date	Implementation Date
Single PDL Implemented	May 2019
Added specific wording for use of Focalin XR® and ProCentra® / November 2019	January 2020
Removed POS information, added Wakix®, formatting changes, updated references / July 2020	July 2020
Modified to apply new age requirement for behavioral health clinical authorization, updated references / September 2020	January 2021
Removed preferred wording for ProCentra®, formatting changes, updated references / November 2020	January 2021
Added wording for Sunosi®, formatting changes / September 2021	October 2021
Added specific wording for use of Adderall XR®, removed specific wording for use of Focalin XR® / October 2021	January 2022